

## EXHIBIT E

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF  
CONFIDENTIALITY

September 12, 2012

11  
12                   Volume I of the transcript of the  
13 Deposition of CHARLOTTE OWENS, M.D., called for  
14 Videotaped Examination in the above-captioned  
15 matter, said deposition taken pursuant to  
16 Superior Court Rules of Practice and Procedure,  
17 by and before JoRita B. Meyer, a Certified  
18 Realtime Reporter, Registered Merit Reporter,  
19 and Certified Court Reporter for the State of  
20 Georgia, at the offices of Troutman Sanders,  
21 600 Peachtree Street Northeast, Atlanta,  
22 Georgia, commencing at 9:39 a.m.

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1 purpose of the IFU?

2 A. The IFU is a document to provide some  
3 general and some specific information to the  
4 physician about the use of our product.

5 Q. Did you understand that the IFU is  
6 considered under FDA regulations to be the  
7 primary label for the medical device, in this  
8 case, the PROLIFT?

9 A. Yes.

10 Q. And you understood this would be the  
11 primary source of information that surgeons  
12 would look to to get information with regard to  
13 the safety and efficacy and potential risks of  
14 using the PROLIFT with patients, correct?

15 A. When you say "primary," what do you  
16 mean by "primary"?

17 Q. Meaning this would be the first --  
18 well, rephrase.

19 When I say "primary," I say that  
20 if -- if there was anything that a surgeon  
21 would look at, it would be this, this would be  
22 the first thing that they would look to?

23 A. I don't know if it's the first thing  
24 that they would look to, because this would  
25 have been part of our entire professional

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1 education package; so this would be one of the  
2 things that they would look to, yes.

3 Q. Do you understand the significance  
4 under FDA regulations of the IFU being the  
5 primary label for the PROLIFT?

6 A. I understand the FDA regulations  
7 around the document. I also understand the way  
8 that physicians are trained and operate.

9 MR. SLATER: Move to strike from "I  
10 also" forward.

11 BY MR. SLATER:

12 Q. What's your understanding as to the  
13 significance of the IFU being the primary label  
14 for the PROLIFT from FDA regulatory standpoint?

15 A. That the agency sees this as the  
16 document that they review as a part of the  
17 packaging for our materials. So it should  
18 contain the relevant indications, description,  
19 and -- and other pertinent information as  
20 prescribed by the regulations.

21 Q. That would also include all necessary  
22 contraindications, warnings and precautions,  
23 and adverse reactions, correct?

24 A. It would include warnings,  
25 precautions, contraindications, adverse

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1 reactions, sterility, disposal, storage,  
2 et cetera.

3 Q. You have understood that all of the  
4 information in the IFU needed to be accurate,  
5 correct?

6 A. Yes.

7 Q. You understood that physicians were  
8 going to rely on the IFU in making decisions  
9 about whether or not to use the PROLIFT in  
10 treating patients, correct?

11 MR. BROWN: Objection.

12 THE WITNESS: Physicians will not  
13 rely solely on the IFU for making their  
14 decisions. Physicians will use the IFU  
15 to help inform them, but they will also  
16 use other information.

17 BY MR. SLATER:

18 Q. You understood physicians would rely,  
19 at least in part, on the PROLIFT IFU in making  
20 decisions about whether they wanted to use that  
21 product, that medical device, that system, in  
22 their patients, correct?

23 MR. BROWN: Objection.

24 THE WITNESS: Physicians will use  
25 this document and other documents to

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1           decide if they want to learn more about  
2           the system, and ultimately will use  
3           their training, education, and  
4           experience, plus this document, to  
5           decide if they want to use it.

6       BY MR. SLATER:

7           Q.    Did you understand that it was  
8           necessary to clearly and unambiguously  
9           communicate all necessary contraindications,  
10          warnings and precautions, and adverse reactions  
11          to physicians through the IFU?

12          A.    I understand the document should be  
13          clear and unambiguous, yes.

14          Q.    Did you understand that it was  
15          necessary for Gynecare, to the extent that a  
16          risk was understood to exist with the PROLIFT,  
17          to communicate it in the IFU as opposed to  
18          assuming that surgeons would figure out that  
19          risk on their own?

20          A.    I don't think you're giving surgeons  
21          enough credit. Surgeons don't have to figure  
22          out the complications of an area that they  
23          operate. Surgeons are trained to know the  
24          complications of the area in which they  
25          operate.



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1 BY MR. SLATER:

2 Q. Does it mean too much tension?

3 A. It's not that simple.

4 Q. How would a surgeon doing the  
5 procedure be able to objectively verify, based  
6 on an objective standard, that they had placed  
7 or not placed the mesh with excessive tension?

8 A. They would be able to look at the  
9 repair after surgery and see if it looks  
10 relaxed or see if it looks like it's under  
11 tension.

12 Q. So that's how they would do it?

13 A. That's generally how it was done.

14 Q. Did you ever perform the PROLIFT  
15 procedure?

16 A. On the cadavers, yes. In live  
17 people, because I was not practicing during my  
18 tenure at Ethicon, no.

19 Q. Did you ever on your own, without any  
20 other surgeon performing the procedure -- did  
21 you ever place Gynemesh in a human's body?

22 A. No.

23 Q. Look at the adverse reactions,  
24 please. It was your understanding that you  
25 needed to list each of the adverse reactions

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1       that were known to you in Medical Affairs in  
2       this section, correct?

3           A.     Yes.

4           Q.     And you understood that if you failed  
5       to list adverse reactions that you were aware  
6       of, that that would render that warning  
7       deficient to some extent, correct?

8           A.     Deficient?

9           MR. BROWN:  Objection.

10          THE WITNESS:  I would say that we  
11       listed the adverse reactions that we  
12       knew were adequate and sufficient for  
13       this document.

14       BY MR. SLATER:

15          Q.     Well, you just said a moment ago you  
16       agreed with me that you understood you were  
17       supposed to list each of the adverse reactions  
18       that you in Medical Affairs knew existed at the  
19       time of launch, correct?

20          A.     We listed the adverse events that we  
21       knew to be directly related to the information  
22       that we had at this time.

23          Q.     Okay.  Were there risks -- well,  
24       rephrase.

25                You see where it says, at the end of